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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,805	12/13/2005	Brad St. Croix	001107.00527	7620

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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,805	ST. CROIX ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 24, 26, 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/6/2010 has been entered.

2. Claims 23, 24, 26 and 27 are pending and will be examined on the merits.

Information Disclosure Statement

3. The information disclosure statement filed 12/06/2010 has been considered. An initialed copy is enclosed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter et al. (J. of Histochemistry and Cytochemistry, Vol. 43, No.8 pp. 791-800, 1995).

6. The Claims are drawn to method of identifying tumor endothelial cells comprising contacting a population of tumor cells in a tissue sample containing endothelial cells with one or more antibodies which bind specifically to secreted protein, acidic, cysteine-rich (SPARC or osteonectin).

7. Porter et al. teach sections of human tumors immunostained with anti-SPARC Mab demonstrate SPARC in renal cell carcinoma, adenocarcinoma of lung, adenocarcinoma of breast, giant-cell tumor of bone, astrocytes in a low grade glioma, and endometrial adenocarcinoma (see Figure 5 and 6). Porter et al. disclose low levels of SPARC expression in normal human tissues. In contrast, there were significantly elevated levels of SPARC in malignant tissue. Porter et al. propose that SPARC expression might contribute to some aspects of tumor progression.

Response to Arguments

8. Applicants argue no extrinsic evidence has been supplied to demonstrate that endothelial cells would necessarily be present in Porter's tissue samples. Applicants state "the mere fact that endothelial cells might possibly be present is not sufficient to meet the legal standard for anticipation by inherency". Applicants argue Porter et al. does not teach the third step of identifying tumor endothelial cells. These arguments have been carefully considered but not found persuasive.

9. Porter et al. disclose "strong reactivity was found in fibrocytes and endothelial cells involved in tissue repair and in invasive malignant tumors, including those of the gastrointestinal tract, breast, lung, kidney, adrenal cortex, ovary, and brain" (see

abstract). In addition Porter et al. discloses that "SPARC might also be involved in the development of a tumor-associated vascular network. A model based on the activity of SPARC in vitro has been proposed, in which the protein reduces the attachment of endothelial cells to ECM and results in an alteration of endothelial cell shape, proliferation, migration and the formation of new cords and tubes" (see page 798, right column, 1st line of 1st full paragraph). Porter et al. explicitly states "in virtually all tumors examined, the tumor cells and/or the associated fibrocytes and endothelial cells contained detectable levels of SPARC" (see page 798, right column, 1st full paragraph). Porter et al. clearly disclose the presence of endothelial cells in the malignant tissue samples evaluated for expression of SPARC (or osteonectin) and therefore anticipate Claims 23 and 26.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 23, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (J. of Histochemistry and Cytochemistry, Vol. 43, No.8 pp. 791-800, 1995) in view of Long et al. (PgPub 20040214241) and Taniguchi et al. (Int. J. Cancer, Vol. 86, pp.799-805, June 2000).

13. The Claims are drawn to method of identifying tumor endothelial cells comprising contacting a population of tumor cells in a tissue sample or bodily fluid containing endothelial cells with one or more antibodies which bind specifically to secreted protein, acidic, cysteine-rich (SPARC or osteonectin) and isolating said tumor endothelial cells.

14. The teachings of Porter et al. are presented in the 102(b) rejection set forth above. Porter et al. does not teach isolating tumor endothelial cells. This deficiency is made up for by Long et al. and Taniguchi et al.

15. Long et al. disclose a method of obtaining a population of cells, from bone marrow, bone (tissue), or peripheral blood cells (bodily fluid), contacting said cells with an antibody, and removing cells of the population that do not immunoreact with said antibody (See sections [0035-0038]). Claims 16 and 18-20 of Long et al. disclose the use of an osteonectin antibody to isolate specific cells.

16. Taniguchi et al. disclose tumor vascular endothelial cells have been identified as a new target for cancer therapy. Tumor vessels are more suitable target than tumor cells for the following reasons: (i) tumor endothelial cells are genetically stable and do not develop acquired drug resistance, (ii) systemically administered drugs have better

access to TECs than tumor cells and (iii) damage of TECs and tumor vessels leads to tumor regression.

17. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the antibody disclosed in Porter et al. or Long et al. to isolate tumor endothelial cells in tissue or bodily fluid samples as described in Long et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Porter et al., Long et al., and Taniguchi et al., because Taniguchi et al. teach tumor endothelial cells have been identified as a new target for cancer therapy and cultures of tumor endothelial cells need to be cultivated by isolating them from tumor samples to test new anti-cancer therapies.

Response to Arguments

18. Applicants argue that Long et al. teach the isolation of bone precursor cells from normal tissue and body fluid, it does not teach or suggest anything at all about tumor endothelial cells or using tumor cells as a population from which to identify endothelial cells. Applicants argue one of ordinary skill in the art who wanted to obtain bone precursor cells would not turn to a population of tumor cells for a source. One of skill in the art would not knowingly choose a malignant cell source for uses as taught by Long, such as treatment of certain bone related disorders and diseases. These arguments have been carefully considered but not found persuasive.

19. The primary reference relied upon in the rejection of record is Porter et al., which clearly disclose the presence of tumor endothelial cells in a population of tumor cells. Long et al. and Taniguchi et al. are supporting references which are relied upon for their method of isolating a specific population of cells (not necessarily bone precursor cells) which could be useful for new anti-cancer therapies. Taniguchi et al. provide motivation for why one of ordinary skill in the art would want to isolate tumor endothelial cells (i.e. tumor endothelial cells need to be cultivated by isolating them from tumor samples to test new anti-cancer therapies). Long et al. disclose a method of how to isolate a specific population of cells which bind to a specific antibody. Therefore, one of ordinary skill in the art, based on the primary teachings of Porter et al. that identify tumor endothelial cells in a population of tumor cells, would perform the method of using an antibody to isolate a specific population of cells, disclosed in Long et al., to isolate said tumor endothelial cells which bind to osteonectin for the use of new anti-cancer therapies, based on the teachings of Taniguchi et al that tumor endothelial cells are beneficial for the development of new anti-cancer therapies. The rejection of record is therefore maintained.

Conclusion

20. Claims 23, 24, 26 and 27 are rejected.

21. No Claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is

(571)270-3058. The examiner can normally be reached on Monday-Friday, 9:00AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Misook Yu/
Supervisory Patent Examiner, Art Unit 1643